

REMARKS

Claim Amendments

Claims 32 and 33 have been cancelled without prejudice to their later presentation in a continuing application. Claims 21 and 27 have been amended to more clearly define the invention and to omit the recitation of a tetrahydropyranol ether modification at only the third carbon. Claims 26 and 31 have each been amended to remove two specifically recited compounds. Claims 25 and 34 have been amended to improve clarity. Claim 35 has been amended to remove the recitation of the symptoms treated in the specifically recited population to whom the hormone is administered. No new matter has been added.

Rejection of Claims 27-31, 33, 34 and 35 Under 35 U.S.C. §112, First Paragraph

Claims 27-31, 33, 34 and 35 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The Examiner states that the specification is enabling for improving weight loss, increasing energy, reducing fatigue, increasing T3 thyroid hormone activity, improving memory, improving muscular wasting and increasing HDL. Without agreeing with the rejection, Applicant notes that claim 27 has been amended to recite the indications for which the Examiner has acknowledged enablement; claims 32 and 33 have been cancelled. Claims 28-31 and 34-35 depend on claim 27 and incorporate its limitations. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection of Claims 27-35 Under 35 U.S.C. §112, Second Paragraph

Claims 27-35 are rejected under 35 U.S.C. §112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention with regard to the recitation of "improving the health" of a human.

Again, without agreeing with the rejection, Applicant notes that claim 27 has been amended to recite that the improvement in health comprises one or more of improving weight loss, increasing energy, reducing fatigue, improving memory, improving muscular wasting, increasing HDL, and increasing T3 thyroid hormone activity. With this amendment the claims more clearly define specific improvement(s) in health achieved by the claimed method. Accordingly it is respectfully requested that the Examiner reconsider and withdraw the rejection.

Rejection of Claims 21, 22, 25 and 26 Under 35 U.S.C. §102(b)

Claims 21, 22, 25 and 26 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Joska *et al.* (Reference V).

Joska *et al.* discloses the synthesis of specific analogues of 5α -androstan- $3\alpha,17\beta$ -diol, 3-keto- 5α -androstan- 17β -ol and androsterone. Claim 21 has been amended to recite a modification selected from the group consisting of a tetrahydropyranol ether at the seventeenth carbon or the third and seventeenth carbons, a 1-methoxycyclopentane ether at the third carbon, the seventeenth carbon or the third and seventeenth carbons, a cyclopent-1'-enyl ether at the third carbon, the seventeenth carbon or the third and seventeenth carbons, and combinations thereof, and wherein said third and seventeenth carbons are not otherwise modified. Claim 26 has been amended to remove the recitation of two specific modified $\Delta 5$ -androstene compounds. Joska *et al.* does not teach any of the currently claimed modified $\Delta 5$ -androstene compounds. Specifically Joska *et al.* does not teach 1-methoxycyclopentane ethers or cyclopent-1'-enyl ethers at either the third or seventeenth carbons and does not teach a tetrahydropyranol ether at both the third and seventeenth carbons.

Accordingly the disclosure of Joska *et al.* does not anticipate the claimed invention as amended. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 21, 22 and 25 Under 35 U.S.C. §102(b)

Claims 21, 22 and 25 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Marwah *et al.* (Reference U).

Marwah *et al.* disclose the preparation of substituted glucuronides, ethers and alkylcarbonates of 7 oxygenated steroids. Claim 21 has been amended to recite a modification selected from the group consisting of a tetrahydropyranol ether at the seventeenth carbon or the third and seventeenth carbons, a 1-methoxycyclopentane ether at the third carbon, the seventeenth carbon or the third and seventeenth carbons, a cyclopent-1'-enyl ether at the third carbon, the seventeenth carbon or the third and seventeenth carbons, and combinations thereof, and wherein said third and seventeenth carbons are not otherwise modified. Marwah *et al.* does not teach any of the currently claimed modified $\Delta 5$ -androstene compounds. Specifically Marwah *et al.* does not teach 1-methoxycyclopentane ethers or cyclopent-1'-enyl ethers at either

the third or seventeenth carbons and does not teach a tetrahydropyranol ether at both the third and seventeenth carbons.

Accordingly the disclosure of Marwah *et al.* does not anticipate the claimed invention as amended. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 21-35 Under 35 U.S.C. §103(a)

Claims 21-35 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Joska *et al.* (Reference V), Marwah *et al.* (Reference U), Lardy *et al.* (U.S. Patent 5,506,223; Reference A) and Pauza *et al.* (U.S. Patent 5,885,977; Reference B) in combination.

As discussed above, neither Joska *et al.* nor Marwah *et al.* disclose the currently claimed modified $\Delta 5$ -androstene compounds. Lardy *et al.* and Pauza *et al.* do not correct this defect. Neither Lardy *et al.* nor Pauza *et al.* disclose ether modifications at the third, seventeenth or third and seventeenth carbons of a $\Delta 5$ -androstene compound. Thus, while Applicant does not concede the propriety of the combination of references, even such a combination fails to teach or suggest the claimed invention because the combination fails to teach or suggest all elements of the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above remarks and amendments, Applicant respectfully submits that the application is in condition for allowance. If the Examiner believes that a telephone call would be useful in expediting the allowance of the application, the Examiner is invited to contact the undersigned.

Applicant believes that no fee is due for the response other than the fees provided for on the accompanying transmittal. However, if an additional fee is due, please charge Deposit Account No. 50-3655, from which the undersigned is authorized to draw, under order number BKNL-001-101.

Dated:

2/11/09

Respectfully submitted,

By Lisa M. Treannie

Lisa M. Treannie, Esq.
Registration No.: 41,368
Morse, Barnes-Brown & Pendleton, P.C.
Reservoir Place
1601 Trapelo Road, Suite 205
Waltham, MA 02451
781-622-5930
Attorneys for Applicant